IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION and MSP SINGAPORE COMPANY LLC, Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LTD., Defendants.	Civil Action No. 07-cv-1334 (JLL)(ES) **FILED ELECTRONICALLY** Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF GLENMARK'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS 1-5 AND 7-13 (DOUBLE PATENTING)

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I. INTRODUCTION

Defendants Glenmark Generics Inc., USA (formerly, Glenmark Pharmaceuticals Inc., USA) and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark") respectfully move for summary judgment that claims 1-5 and 7-13 of U.S. Patent No. RE37,721 ("the '721 patent") are invalid for obviousness-type double patenting.[1] Plaintiffs Schering Corp. and MSP Singapore Co. LLC (collectively, "Schering") allege that Glenmark has infringed the '721 patent by filing an Abbreviated New Drug Application for generic ezetimibe, a cholesterol lowering drug. Ezetimibe is the active ingredient in the drug product Zetia, which is marketed in the United States by MSP Singapore Co. LLC.

The '721 patent claims azetidinone compounds[2], including ezetimibe, as well as pharmaceutical compositions and methods of treatment with these azetidinone compounds. In addition to the '721 patent, Schering obtained an earlier issued patent, U.S. Patent No. 5,631,365 ("the '365 patent"), directed to methods of preparing these azetidinone compounds. The '365 patent is set to expire on May 20, 2014, while the '721 patent will not expire until October 25, 2016.[3]

The central concern in a double patenting analysis is one of duration - namely, how long should the patent protection on ezetimibe and related compounds and processes for making these compounds be permitted to extend. Under the proper analysis, patent protection should expire on May 20, 2014.

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[1] Glenmark has an alternative argument in support of this defense that relies on expert testimony. This alternative argument is not addressed in this motion and will be presented if required at trial.

[2] The term "azetidinone" refers to a particular four member ring system consisting of three carbon atoms and one nitrogen atom.

[3] The term of the '721 patent was extended pursuant to a patent term extension under 35 U.S.C. §156. (Exhibit F). The original expiration date of the '721 patent was June 16, 2015.

Non-statutory double patenting was developed to prevent "an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later." *In re Berg*, 140 F.3d 1428, 1431-1432 (Fed. Cir. 1998); *see also Geneva Pharms., Inc. v. GlaxoSmithKline PLC,* 349 F.3d 1373, 1378 (Fed. Cir. 2003); *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). The present case presents the exact "unjustified extension" of an earlier patent that the doctrine of non-statutory double patenting was designed to prevent.

From the issuance of the '365 patent in May 1997, until its expiry in May 2014, Schering will have had exclusive rights over the processes claimed. Even after expiration of the '365 patent, however, Schering will still command exclusive rights over the processes claimed because practicing that process for the vast majority of compounds, including the more than thirty compounds exemplified in the patent, results in the production of a compound covered by at least one claim of the '721 patent. Thus, Schering has extended the term of the right to exclude, afforded by processes claimed in the '365 patent, by virtue of its later '721 patent, which does not expire until October 25, 2016.

Schering has unjustifiably denied the public access to lower-cost, generic ezetimibe by asserting the compound, pharmaceutical composition, and method of treatment claims in the later '721 patent, which claim nothing more than obvious variations of the claimed processes of the '365 patent. This contravenes "the policy that the public should be free to use the invention as well as any obvious modifications at the end of the patent's term." *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) (*citing In re Robeson*, 331 F.2d 610, 614 (C.C.P.A. 1964)). The unjustified extension of Schering's exclusive rights through the '721 patent thwarts both the patent system

and the public interest. Rectifying such inequity is the very purpose of the doctrine of non-statutory double patenting. *See Longi*, 759 F.2d at 892-93.

Schering should not be permitted to improperly extend its patent monopoly. Glenmark respectfully requests that this Court prevent this improper time-wise extension by holding claims 1-5 and 7-13 of the '721 invalid for obviousness-type double patenting.

There are no material facts in dispute. This issue is ripe for summary judgment of invalidity of claims 1-5 and 7-13.

II. FACTUAL BACKGROUND

Glenmark assumes the following facts taken in the light most favorable to Schering.

A. The '365 Patent and its Prosecution History

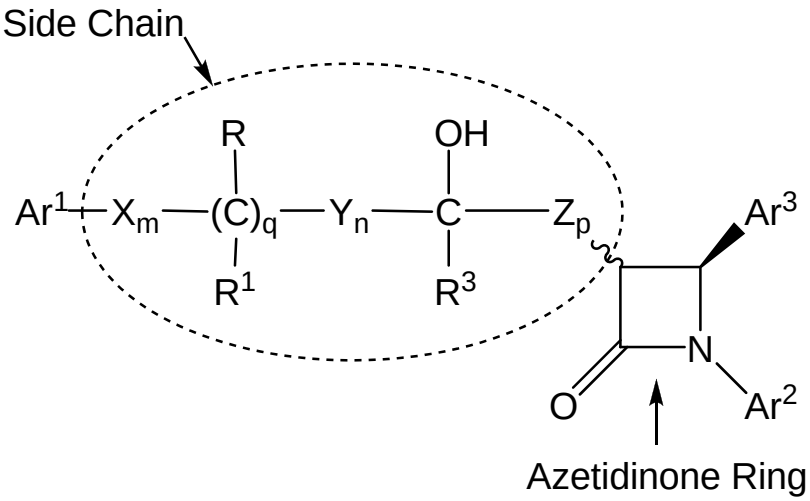
1. The Claims of the '365 Patent

The '365 patent includes four claims directed to methods of preparing azetidinone compounds. (Ex. A[4], SPZ000332072-73). The method recited in claim 1 includes the steps of (a) treating a lactone compound with a strong base, (b) reacting the product of step (a) with an imine, (c) quenching the reaction with an acid, and (d) removing, as necessary, a protecting group. (*Id.* at SPZ000332072). Claim 2 depends from claim 1 and further includes a step of converting a hydroxy or amino substituent on the azetidinone compound to one of a group of other chemical moieties. (*Id.*).

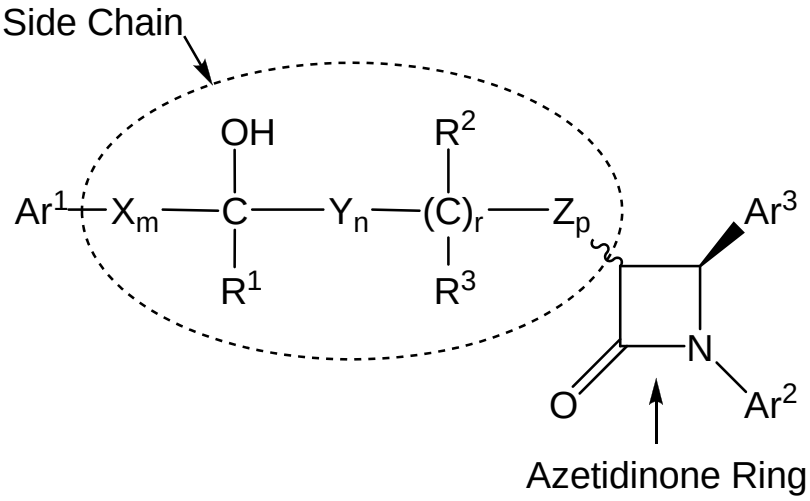
The azetidinone compounds formed by the method recited in claims 1 and 2 have the formula shown below. (*Id.*). The chemical group (or moiety) between the azetidinone ring and

[4] Citations to "Ex. __" are references to the exhibits to the *Declaration of George Hykal in Support of Glenmark's Motion for Summary Judgment of Invalidtity of Claim 1-5 and 7-13 (Double Patenting)*, which is being filed and served with this memorandum of law.

the Ar^1 group is known as a side chain. The side chain of the azetidinone compounds made by this process has a chain length of 2-7 atoms.[5]



Independent claim 3 is nearly identical to claim 1 but uses a different lactone compound in step (a) and produces compounds having the formula below. (*Id.* at SPZ000332072-73). Claim 4 depends from claim 3 but is otherwise identical to claim 2. (*Id.*). The side chain of the azetidinone compounds formed by the process recited in claims 3 and 4 also has a chain length of 2-7 atoms.



[5] The chain length is determined by counting the number of atoms connecting the azetidinone group to the Ar^1 group.

The patent states that the azetidinone compounds are useful as hypcholesterolemic agents, and can be used to treat or prevent atherosclerosis and reduce serum cholesterol levels (*see, e.g., Id.* at SPZ000332053-54, col. 1, lines 9-14, col. 2, line 15, col. 3, lines 33-38).

2. Prosecution History of the '365 Patent

The '365 patent was filed as U.S. Serial No. 08/257,593 ("the '593 application") on June 9, 1994. (Ex. B, SPZ000000452). The '593 application included biological data showing the effects of thirty-two azetidinone compounds on cholesterol ester and serum cholesterol levels in hamsters. (*Id*. at SPZ000000493). This data, which is reproduced below, was reported on page 39 of the specification. (*Id*.). Compound 6A is ezetimibe. (Ex. A, SPZ000332069, col. 33, lines 14-20).

	% Reduction				% Reduction		
Ex. #	Serum Cholest.	Cholest. Esters	Dose mg/kg	Ex. #	Serum Cholest.	Cholest. Esters	Dose mg/kg
1A	-23	0	50	4C	-12.5	0	3
1B	-15	-39	50	4D	9	0	7
1C	14	0	50	4E	0	-46	3
2	0	0	50	4F	-29	-95	3
3A	-31	-69	50	5	0	-64	10
3C	-60	-92	50	6A	-59	-95	1
3D	-17	-61	10	6B	-40	-92	3
3E	0	0	10	6C	0	-48	3
3F	-29	-77	10	6D	-46	-95	10
3G	-16	-38	10	8A	0	-44	3
3H	-41	-86	10	8B	-50	-95	3
3I	0	-22	10	8C	-14	-37	1
3J	0	0	3	8D	-49	-98	1
3K	0	0	10	8E	-22	-66	3
4A	0	-54	5	8F	-43	-94	1
4B	-37	-89	8	10	-26	-77	3

Schering was orally informed of a restriction requirement in the '593 application. (Ex. B, SPZ000000525-530). Specifically, the Patent Office required election between three groups of inventions for further prosecution in the '593 application: (I) claims drawn to compounds and simple compositions, (II) claims drawn to complex compositions and a kit, and (III) claims drawn to methods of preparing the compounds. (*Id*. at SPZ000000526). On November 7, 1994, Schering's counsel orally elected the claims of group (III), i.e., the method of preparation claims. (*Id*. at SPZ000000527). The restriction requirement was subsequently mailed on November 21, 1994 with the results of the substantive examination of the elected claims. (*Id.* at SPZ000000525-530). In response to the November 21, 1994 Office Action, Schering canceled the claims to the two non-elected groups of inventions. (*Id.* at SPZ000000534-541).

The claims of the '593 application were later rejected for lacking enablement under 35 U.S.C. §112, ¶ 1. (*Id.* at SPZ000000576-577). The Patent Examiner argued that the azetidinone compounds made by the claimed process "by and large" do not lower cholesterol:

> Claims 25, 27, 29, [and] 31 are rejected [under] 35 USC 112, paragraph 1, for lack of enablement. The compounds are alleged to lower serum cholesterol. Yet applicant's own evidence is that, by and large, they do not. The page 29 data can be summarized as follows:
>
> > No reduction (0%) or actually raises level: 12
> > Doubtful efficacy (1-24%): 7
> > Effective (25+%): 13
>
> Claims must be limited to species which are enabled, In re Harwood, 156 USPQ 673. The preparation of compounds with no utility itself lacks utility, Breenen [sic: Brenner] vs Manson, 148 USPQ 693.

(*Id.* at SPZ000000577). Specifically, the Examiner pointed out that twelve of the thirty-two compounds for which biological data is reported in the '365 patent did not reduce serum cholersterol or, in fact, raised it. (*Id.*). The Patent Examiner also correctly pointed out that a

process for preparing compounds having no utility, itself lacks utility, one of the basic requirements for obtaining patent protection.[6] (*Id.*).

To overcome this rejection, Schering repeatedly argued that the biological data for the thirty-two compounds, including ezetimibe, provided at page 39 of the specification demonstrated that the compounds made by the claimed process lower cholesterol esters. In a November 20, 1995 response, Schering argued:

> Applicants respectfully submit that the compounds prepared by the instantly claimed processes are shown in the specification to have utility. …
>
> The data provided on page 39 [of the specification] demonstrates that compounds made by the claimed process lower cholesterol esters. … Applicants respectfully submit that the data on page 39 of the specification showing decreases in serum cholesterol and cholesterol esters are sufficient to support the utility of the compounds as hypcholesterolemic agents, and therefore a process for preparing a genus of related compounds is enabled.

(*Id*. at SPZ000000578, 579, 581). Again, in a May 8, 1996 response, Schering argued:

> Data provided in the instant specification on page 39 demonstrate that the compounds made by the claimed process reduce hepatic cholesterol ester levels, therefore reducing cholesterol absorption and consequently reducing serum cholesterol.

(*Id.* at SPZ000000591).

Schering also submitted a declaration from one of its scientists to support its assertion that the biological data on page 39 of the specification supported the utility of the azetidinone compounds:

> The subject patent application states on page 22, lines 4 to 12, that the compounds made by the process claimed in the application inhibit intestinal absorption of

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[6] *Brenner v. Manson*, 383 U.S. 519, 534-535 (1966) ("Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. … Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field").

> cholesterol and reduce the formation of liver (hepatic) cholesterol esters, and data showing reduction of cholesterol esters is shown on page 39; one skilled in the art will recognize, therefore, that compounds made by the process of this invention will lower serum cholesterol.

(*Id.* at SPZ000000597).

After the submission of the May 8, 1996 response and declaration, the '593 application was allowed by the Patent Office. (*Id.* at SPZ000000604-605). The '593 application issued as the '365 patent on May 20, 1997. (Ex. A, SPZ000332052). The '365 patent will expire on May 20, 2014.[7]

B. The International Application

On September 14, 1994, Schering filed an International application (PCT/US94/10099) which was a continuation-in-part application of the '593 application.[8] (Ex. C, p. 1). The specification of the International application is virtually identical to that of the '593 application, except the International application further includes two additional synthetic examples (Examples 3L and 3M) and provides *in vivo* data for the compounds prepared in these new examples as well as for compound 6A-1. (Compare Ex. B, SPZ000000452-504 with Ex. C)

C. The '721 Patent

The International application entered the U.S. national phase and matured into U.S. Patent No. 5,767,115 ("the '115 patent"). (Ex. D, SPZ000335537, 538, col. 1, lines 5-8).

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[7] For applications that were pending on June 8, 1995, the patent term is either seventeen years from the issue date or twenty years from the filing date of the earliest U.S. application to which priority is claimed, the longer term applying. 35 U.S.C. §154(c).

[8] A continuation-in-part application "continues subject matter disclosed in a prior application, but it adds new subject matter not disclosed in the prior application." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008) (*quoting Univ. of W. Va. Bd. of Trs. v. Van Voorhies*, 278 F.3d 1288, 1297 (Fed. Cir. 2002)); *see also* the Manual of Patent Examining Procedure ("MPEP") §201.08 (8th ed., Rev. 7, 2008) ("A continuation-in-part is an application filed during the lifetime of an earlier [patent] application, repeating some substantial portion or all of the earlier [patent] application and *adding matter not disclosed* in the said earlier [patent] application") (emphasis in original).

Accordingly, the U.S. application, which matured into the '115 patent on June 16, 1998, has the same filing date as the International application, i.e., June 9, 1994.[9] (*Id.*).

On June 15, 2000, Schering filed reissue application 09/594,996, which issued as the '721 Patent on May 28, 2002. (Ex. E, SPZ000000001). The '721 Patent retains the nine original claims from the '115 Patent, adding four "bullet" claims intended to focus on just the ezetimibe compound. (Compare Ex. D, SPZ000335556-57 with Ex. E, SPZ000000021-022). The '721 Patent has thirteen claims. (Ex. E, SPZ000000021-022).

Independent claim 1 is directed to a genus of azetidinone compounds. (*Id.* at SPZ000000021). This genus encompasses all of the azetidinone compounds which can be prepared by the processes claimed in the '365 patent, except for the compounds having a side chain length of 7 (i.e., the azetidinone compounds have a side chain length of 2-6).[10] (Compare Ex. E, SPZ000000021 with Ex. A, SPZ000332072-73). Claims 2-5 of the '721 Patent depend from claim 1 and further narrow the genus. (Ex. E, SPZ000000021). Each of claims 1-5 covers ezetimibe. (*Id.*). Independent claim 7 covers twenty-four compounds, including ezetimibe. (*Id.* at SPZ000000021-022). Claim 8 is directed to a pharmaceutical composition comprising an effective amount of a compound of claim 1 in a pharmaceutically acceptable carrier. (*Id.* at SPZ000000022). Claim 9 is directed to a method of treating or preventing atherosclerosis or

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[9] Manual of Patent Examining Procedure ("MPEP") §1893.03(b) ("It should be borne in mind that the filing date of the international stage application is also the filing date for the national stage application"); 35 U.S.C. §363 ("An international application designating the United States shall have the effect, from its international filing date …, of a national application for patent regularly filed in the Patent and Trademark Office except as otherwise provided in section 102(e) of this title").

[10] The side chain length of the azetidinone compounds in claim 1 of the '721 patent is determined by the sum of variables m, n, p, q, and r, which according to the claims ranges from 2 to 6. (Ex. E. SPZ000000021, col. 37, line 62).

reducing plasma cholesterol levels by administering to a mammal in need of such treatment an effective amount of claim 1. (*Id.*).

Claims 10 and 11 are directed to ezetimibe and pharmaceutically acceptable salts thereof. (*Id.*). Claims 12 and 13 are identical to claims 8 and 9 but are limited to ezetimibe and pharmaceutically acceptable salts thereof. (*Id.*).

The '721 patent issued on May 28, 2002. (*Id.* at SPZ000000001). The original expiration date of the '721 patent was June 16, 2015[11], more than a year after expiration of the '365 patent (May 20, 2014). Schering obtained a patent term extension of 497 days, which extends the term of the '721 patent to October 25, 2016. (Ex. F).

III. STANDARD OF LAW

A. Summary Judgment

Summary judgment is appropriate when there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Paragon Podiatry Laboratory, Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993). A material fact is one that may affect the decision, so that finding that fact is necessary to the proceedings. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). There is a genuine issue only if sufficient evidence is presented such that a reasonable fact finder could find for the non-moving party. *Liberty Lobby*, 477 U.S. at 248. "Summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1379 (Fed. Cir. 2002).

[11] June 16, 2015 is seventeen years after the '115 Patent issued on June 16, 1998. *See* fn. 7, *supra*.

B. Double Patenting

The doctrine of double patenting is intended to prevent a patentee from obtaining an improper time-wise extension of a patent for the same invention or an obvious modification thereof. *In re Lonardo*, 119 F.3d at 965 (Fed. Cir. 1997); *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991). The Federal Circuit has explained the underlying policy as follows:

> The public should . . . be able to act on the assumption that upon the *expiration* of [a] patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and prior art other than the invention claimed in the issued patent. (Emphasis in original)

Longi, 759 F.2d at 892-893 (*quoting In re Zickendraht*, 319 F.2d 225, 232 (1963) (Rich, J., concurring)).

There are two types of double patenting: statutory and non-statutory. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). Statutory double patenting, also referred to as "same invention" double patenting, is premised on 35 U.S.C. §101 and prevents an applicant from obtaining more than one patent on the same invention. *Id.* at 1372-73; *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970). Glenmark is not asserting a defense of statutory double patenting in this lawsuit.

Non-statutory double patenting, also referred to as "obviousness-type" double patenting, is a judicially-created doctrine. A claim is invalid for obviousness-type double patenting if it is merely an obvious variation of the earlier claim as considered from the vantage point of an ordinarily skilled artisan. *In re Basell Poliotefine Italia S.p.A.*, 547 F.3d 1371 (Fed. Cir. 2008). Glenmark's summary judgment motion is premised on this type of double patenting.

Generally, an obviousness-type double patenting analysis involves two steps. First, a court construes the claims in the earlier and later issued patents and determines any differences.

Second, the court determines whether those differences render the claims patentably distinct. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Id*. at 968 (*citing Longi*, 759 F.2d at 896). Where the later claim is not patentably distinct from the earlier claim, the later claim is invalid for non-statutory double patenting.

The specification of a patent may be used in a double patenting analysis under certain circumstances. For instance, tangible embodiments of the claimed invention provided in the specification of the earlier issued patent can be used in a double patenting analysis and compared to the later claims to determine whether the later claims are merely obvious variations of these embodiments. *See In re Basell Poliolefine Italia S.pA.*, 547 F.3d 1371, 1378-79 (Fed. Cir. 2008). In *Basell*, the Federal Circuit explained this permitted use of the specification in detail:

> our predecessor court stated that a patent's disclosure may be used to determine whether an application claim is merely an obvious variation of an invention claimed in a patent. (*In re Vogel*, 422 F.2d 438, 441-42 (CCPA 1970)). The court stated that the disclosure may be used to learn the meaning of terms and in "interpreting the coverage of [a] claim." Id. at 441. It may also be used to answer the question whether claims merely define an obvious variation of what is earlier disclosed and claimed. The court stated that the disclosure "sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether [something] has been modified in an obvious manner." Id. at 442. The court further stated that "use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. §103, since only the disclosure of the invention claimed in the patent may be examined." Id.

Bassel, 547 F.3d at 1378-79 (emphasis added).

Because claims only define a legal boundary, it is less difficult and more meaningful to judge whether a later patent claims an obvious variant by looking at a tangible embodiment of the earlier claimed invention which is disclosed in the earlier patent's specification:

> We recognize that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim. A claim is a group of words defining only the boundary of the patent monopoly. It may not describe any physical thing and indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary? The disclosure, however, sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner. It must be noted that this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.

In re Vogel, 422 F.2d at 442.

Thus, when the disclosure of an earlier issued patent contains an embodiment that provides support for the claims of that patent, a later claim that covers that embodiment constitutes double patenting as to that embodiment. *See In re Schneller*, 397 F.2d 350, 354-56 (CCPA 1968). In such a case, looking to the specification of the earlier issued patent to identify an embodiment that supports – and is thus covered by – the earlier issued claims is perfectly appropriate. *See In re Vogel*, 422 F.2d at 442. This is because allowing a second patent on the same embodiment would give the patentee an improper time-wise extension of rights in that embodiment, which should naturally have fallen into the public domain upon expiration of the earlier issued patent. *Id.* at 442-43. As explained by the *Schneller* court:

> The controlling fact is that patent protection for the [embodiment], fully disclosed in and covered by the claims of the patent, would be extended by allowance of the appealed claims. Under the circumstances of the instant case, wherein we find no valid excuse or mitigating circumstance making it either reasonable or equitable to make an exception, and wherein there is no terminal disclaimer, the rule against 'double patenting' must be applied.

Schneller, 397 F.2d at 355.

1. Obviousness-type double patenting is distinct from the defense of obviousness

There are at least three distinctions between an obviousness-type double patenting analysis and a statutory obviousness analysis pursuant to 35 U.S.C. §103. First, statutory

obviousness compares claimed subject matter to the prior art, while non-statutory double patenting compares claims in an earlier patent to claims in a later patent or application. Second, double patenting does not require inquiry into a motivation to modify the prior art. Finally, double patenting does not require inquiry into objective criteria suggesting non-obviousness. *P&G v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009); *Geneva Pharms.*, 349 F.3d at 1377 n. 1.

2. The double patenting safe harbor provided by 35 U.S.C. §121 is only available for divisional applications

35 U.S.C. §121 provides a safe harbor with respect to double patenting to patents that issue from applications filed as a result of a restriction requirement. In pertinent part, 35 U.S.C. §121 states:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

Therefore, under 35 U.S.C. §121, a patent is shielded from the use of an earlier issued patent as a reference only if the later issued patent (1) was filed as a result of a restriction requirement in the earlier issued patent, and (2) is consonant with that restriction requirement. *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347-48 (Fed. Cir. 2004) ("As section 121 has been interpreted by this court, Bristol-Myers is entitled to invoke the statutory prohibition against the use of the [earlier] patent 'as a reference' against the divisional application that resulted in the [later] patent only if the divisional application was filed as a result of a restriction requirement and is consonant with that restriction requirement.").

The protections afforded by 35 U.S.C. §121, however, are limited to divisional applications and do not apply to continuation-in-part (CIP) applications. *Pfizer*, 518 F.3d at

1362 ("We conclude that the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications. ... Here, the [later] patent ... was filed as a CIP and not a divisional application. We hold that section 121 does not apply to the [later] patent and that the [earlier] patent may be used to invalidate the [later] patent.").

IV. ARGUMENT

Schering has obtained an unjustified time-wise extension of the '721 patent. The claims of the '721 patent are patentably indistinct from those of the earlier issued '365 patent. The '365 patent claims methods of preparing azetidinone compounds. (Ex. A , SPZ000332072-73). All of the azetidinone compounds exemplified in the '365 patent as well as the vast majority of azetidinone compounds which can be prepared by the methods claimed in the '365 patent are covered by the '721 patent. (Compare Ex. A, SPZ000332063-071 with Ex. E, SPZ000000021-22). Consequently, upon expiration of the '365 patent, the public cannot perform the claimed methods to make any of the azetidinone compounds exemplified in the patent, nor most other compounds encompassed by the '365 patent. The claims of the '721 patent are, therefore, directed to an obvious variant of the methods of preparation claimed in the '365 patent. Accordingly, claims 1-5 and 7-13 of the '721 patent are invalid for obviousness-type double patenting over claims 1-4 of the '365 patent.

A. Construction of the Claims of the '365 and '721 Patents

The first step of a non-statutory double patenting analysis involves construing the claims of the earlier and later patents. *Eli Lilly*, 251 F.3d at 968. Two terms in the claims of the '721 patent were construed by the Court in a September 15, 2008 Decision and Order. *See* Docket Item Nos. 90, 92. The construction of other terms in the claims of the '721 patent was agreed

upon by the parties and attached as Exhibit A to defendants' opening claim construction brief submitted on January 14, 2008.[12] *See* Docket Item No. 43-3. For the purpose of this analysis, it is sufficient to understand that claims 1-5, 7, 10, and 11 cover numerous azeditinone compounds, including ezetimibe.

The claims of the '365 patent are directed to methods of preparing azetidinone compounds. (Ex. A, SPZ000332072-73). Independent claims 1 and 3 of the '365 patent recite methods for preparing an azetidinone compound having a hydroxy group on its side chain. (*Id.*). The methods include (a) treating a lactone compound with a strong base, (b) reacting the product of step (a) with an imine, (c) quenching the reaction with an acid, and (d) removing, as necessary, a protecting group. (*Id.*). Claims 2 and 4 depend from claims 1 and 3, respectively, and include a further step of converting a hydroxy or amino substituent at certain positions on the azetidinone compound produced by the method of claim 1 or 3, to any one of the groups recited in claims 2 and 4. (*Id.*).

B. Differences Between Claims 1-4 of the '365 Patent and Claims 1-5 and 7-13 of the '721 Patent

After properly construing the claims at issue, the double patenting analysis requires comparison of the earlier and later claims to determine what differences exist. *Eli Lilly*, 251 F.3d at 968.

The definitions of all the variables (for instance, Ar^1, Ar^2, and Ar^3) for the azetidinone compound recited in claims 1 and 2 of the '365 patent, when taken together, are identical to the definitions of the same variables in claim 1 of the '721 patent, except for the variables m, n, p, q

[12] The construction of claims 8 and 12 is provided on pages 13 and 14 of Plaintiffs' Responsive Brief in Opposition to Defendants' Opening Markman Brief dated February 12, 2008 (Docket Item No. 47).

and r.[13] (Compare Ex. A, SPZ000332072-73 with Ex. E, SPZ000000021). As a result of the differences in the definitions of these variables, the compounds recited in the '365 and '721 patent claims can have different side chain lengths. In particular, the side chain length of the compounds within claim 1 of the '721 patent is 2-6, while the compounds produced by the methods recited in the claims of the '365 patent have a side chain length of 2-7.[14] Claim 1 of the '721 patent does not cover compounds having a side chain length of 7, while the claims of the '365 patent cover methods of preparing such compounds. In summary, all of the compounds produced by the claims of the '365 patent fall within the scope of claim 1 of the '721 patent, except for those having a side chain length of 7.

Claims 2-5 of the '721 patent recite narrower definitions for certain variables. (Ex. E, SPZ000000021). All of these claims encompass ezetimibe. (*Id.*). Claim 7 recites twenty-four specific compounds, including ezetimibe. (*Id.* at SPZ000000021-22). Claims 10 and 11 specifically recite ezetimibe. (*Id.* at SPZ000000022). The claims of the '365 patent do not specifically recite these narrower definitions or ezetimibe. (Ex. A, SPZ000332072-73).

Claims 8, 9, 12, and 13 of the '721 patent are directed to a pharmaceutical composition and a method of medical treatment with an azetidinone compound of claim 1 or ezetimibe

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[13] This is also the case for claims 3 and 4 of the '365 patent when taken together.

[14] The azetidinone compounds encompassed by claim 1 of the '721 patent have a side chain length of 2-6. The number of atoms between the azetidinone ring and the Ar^1 group in claim 1 of the '721 patent is determined by the sum of the variables m, n, p, q, and r, which must be 2, 3, 4, 5, or 6 (['721 patent] col. 37, lines 63-64). In other words, the side chain length of the '721 claim 1 compounds is 2-6.

In '365 claims 1 and 2, one carbon atom is fixed in place. This is equivalent to setting the variable r in '721 claim 1 to one. Similarly, in '365 claims 3 and 4, the carbon atom at the position of the variable q is fixed in place. The '365 claims require that the sum of the remaining variables (m, n, p, and q in claims 1 and 2 and m, n, p, and r in claims 3 and 4) total 1-6. This results in a side chain length of 2-7.

specifically. (Ex. E, at SPZ000000022). The claims of the '365 patent do not explicitly recite a pharmaceutical composition or a method of medical treatment. (Ex. A, SPZ000332072-73).

C. The Claims of the '721 Patent are Patentably Indistinct From Those of the '365 Patent

The specification of an earlier issued patent, such as the '365 patent, "may be used to answer the question whether claims [of a later patent] merely define an obvious variation of what is earlier disclosed and claimed." *In re Basell Poliolefine Italia S.pA.*, 547 F.3d at 1378; *see also In re Vogel*, *supra*. As explained by the Court of Appeals for the Federal Circuit:

> A claim is a group of words defining only the boundary of the patent monopoly. It may not describe any physical thing and indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary? The disclosure, however, sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner. It must be noted that this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.

In re Vogel, 422 F.2d at 442.

The invention claimed in the '365 patent is a process for preparing certain azetidinone compounds. (Ex. A, SPZ000332072-73). These azetidinone compounds are asserted to be novel and useful as hypocholesterolemic agents. (Ex. A, SPZ000332053, col. 1, lines 9-15, col. 2, lines 15-24). During prosecution of the '365 patent, Schering relied on data for thirty-two compounds, including ezetimibe, to establish the patentability of the claimed process. (Ex. B, SPZ000000493). Accordingly, ezetimibe is a tangible embodiment of a product of the claimed process.

During prosecution of the '365 patent, the Examiner rejected the process claims for lack of enablement under 35 U.S.C. §112, ¶ 1, stating that "by and large" the *in vivo* data provided in the '365 specification does not show that the tested compounds lower serum cholesterol, the sole

use for the compounds. (*Id.* at SPZ000000576-577). Relying on *Brenner v. Manson*, the Examiner further pointed out that the "preparation of compounds with no utility itself [sic] lacks utility." (*Id.* at SPZ000000577); *Brenner*, 383 U.S. 519, 529-529, 534-535 (1966) ("one may patent only that which is 'useful.'" and "Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field") (holding a claim to a chemical process lacks utility where the final product lacks utility).

In response, Schering relied on the data in the specification for the azetidinone compounds, including ezetimibe (compound 6A), showing a reduction in cholesterol esters upon administration to hamsters. (Ex. B, SPZ000000578, 579, 581, 591, 597). Schering, therefore, acknowledged that the preparation of ezetimibe is a tangible embodiment of the claimed process.[15] Accordingly, the disclosure of ezetimibe in the '365 patent is available in the double patenting analysis to assess whether the claims of the '721 patent merely define an obvious variation of what was earlier disclosed and claimed in the '365 patent. Claims covering the compound ezetimibe (claims 1-5, 7, 10, and 11) are therefore obvious over the claims of the '365 patent. *See LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1359 (Fed. Cir. 2001) (where "one of ordinary skill in the art would have been motivated to use the teachings of a prior art process, in its normal disclosed operation, to create a product that a patentee claims in a subsequent patent, then such patent [is] obvious over the former disclosed process").

Claims 9 and 13 of the '721 patent, which are directed to methods of treatment with the azetidinone compounds or ezetimibe in particular, are similarly obvious over the claims of the

[15] Although all thirty-two compounds from the specification of the '365 patent are actually claimed in the '721 patent generically and/or specifically, Glenmark focuses on ezetimibe because it is covered by all of claims 1-5 and 7-13.

'365 patent. "[A] method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline plc*, 349 F.3d 1373, 1385 (Fed. Cir. 2003). As the Federal Circuit's predecessor explained:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

In re Byck, 18 C.C.P.A. 1208, 48 F.2d 665, 666 (CCPA 1931). The Federal Circuit expounded on this reasoning in *Geneva*:

> In *Christmann*, our predecessor court affirmed the PTO's nonstatutory double patenting rejection of claims to an insecticidal composition over a prior patent claiming the composition's active component. *In re Christmann*, 29 C.C.P.A. 1037, 128 F.2d 596, 1942 Dec. Comm'r Pat. 481 (CCPA 1942). Our predecessor court stated that the applicant could only have obtained a patent by disclosing the composition's utility, and "such disclosure of usefulness did not constitute separate inventions, but an essential part of a single invention." Id. at 600 (quoting Byck).
>
> These cases apply as well to this court's review of the [method of treatment] patent and the earlier [compound] patent. The [compound] patent's claim describes a compound, and [the patent]'s written description discloses a single utility of that compound as administration to a human in amounts effective for inhibiting beta-lactamase. The [method of treatment] patent claims nothing more than [the compound patent]'s disclosed utility as a method of using the compound. Thus, the claims of the [compound] and [method of treatment] patents are not patentably distinct.

Geneva, 349 F.3d at 1385.

Here, Schering was only able to obtain the '365 patent by disclosing the utility of the azetidinone compounds prepared by the claimed process. The only disclosed uses of the azetidinone compounds in the '365 patent are for treating or preventing atherosclerosis and reducing plasma cholesterol levels, the very same uses recited in claims 9 and 13 of the '721 patent. (Ex. A; Ex. B). This "disclosure of usefulness did not constitute separate inventions, but

an essential part of a single invention." *Geneva*, 349 F.3d at 1385 (quoting *Christmann*, 128 F.2d at 600). Thus, the uses disclosed in the '365 patent for the compounds prepared by the processes claimed can be used in a double patenting analysis.

With knowledge of the use of these compounds as hypocholesterolemic agents, it would have been obvious to incorporate the compounds, including ezetimibe, of the '365 patent into a pharmaceutical composition, as recited in claims 8 and 12 of the '721 Patent, to facilitate administration of them to patients.

For at least these reasons, claims 1-5 and 7-13 of the '721 patent are obvious variants of the processes claimed in the '365 patent.

D. Obviousness-type double patenting can exist between product and process claims

Schering relies on *General Foods Corp. v. Studiengesellschaft Kahle mbH*, 972 F.2d 1272 (Fed. Cir. 1992) for the proposition that product claims can never be invalid for obviousness-type double patenting over process claims in an earlier issued patent.[16] Specifically, Schering relies on the statement in *General Foods* that:

> comparison can be made only with what invention is claimed in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim defines and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.

General Foods, 972 F.2d at 1280. This holding from *General Foods* is inapplicable here because Glenmark does not ask this Court to look to claims of the prior patent "for anything that happens to be mentioned in it as though it were a prior art reference." Rather, Glenmark asks this court to look at an embodiment resulting from the process claims in the earlier patent

[16] Schering also relies on *Astellas Pharma, Inc. v. Ranbaxy Inc.*, Civ. A. No. 05-2563, 2007 WL 567341, at *4-5 (D.N.J. Feb. 21, 2007) for this proposition. This decision, however, has been vacated. *See* Ex. G.

(ezetimibe) and hold that a claim for that same embodiment in a later issued patent is not patentably distinct.

The law is well-established that non-statutory double patenting can exist between product and process claims. *Geneva Pharms.*, 349 F.3d at 1385-86 (later claim to a method of use held invalid for non-statutory double patenting in view of an earlier claim to a compound); *In re Freeman*, 166 F.2d 178, 179 (C.C.P.A. 1948) (later claim to a product held invalid for double patenting over an earlier claim to a process for making the product); *In re Byck*, 48 F.2d 665, 666 (CCPA 1931) (claim to method of using a composition held invalid for double patenting over earlier claim to composition); *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 562 F.Supp.2d 619 (D. Del. 2008) (finding claims to compounds held invalid for obviousness-type double patenting over earlier patent to methods of treatment with the compounds). Thus, product claims are not *per se* patentably distinct from process claims.

In *In re Freeman*, the court found that later composition claims were invalid for double patenting over earlier process claims. *See Freeman*, 166 F.2d 178 (C.C.P.A. 1948). The later claims were directed to a coating composition while the earlier claims were directed to a process for making the oil that was the essential element of the later claimed composition. *Id*. at 179. The Court analyzed and compared the later compositions and the earlier processes, and ultimately concluded that the later composition claims were invalid for double patenting. *Id*. at 180-81. Thus, at the very least, *Freeman* establishes that later product claims are not *per se* patentably distinct from earlier process claims.

E. Secondary indicia of non-obviousness are not probative of whether the '721 Patent claims are patentably distinct over the '365 Patent

This Court should not consider objective indicia of non-obviousness in the present obviousness-type double patenting analysis. *See P&G*, 566 F.3d at 999; *Geneva*, 349 F.3d at

1377 n. 1. Objective indicia, such as commercial success, failure of others, long felt need, and praise by others, are not probative of the non-obviousness of the claims of the '721 patent as the tangible embodiment in the '365 patent used for this analysis is ezetimibe itself.

F. The '721 Patent is Not Entitled to Double Patent Shielding Provided By 35 U.S.C. §121

It is undisputed that the '721 patent matured from a continuation-in-part application of the '593 application, which issued as the '365 patent. The lineage of the '721 patent set forth above is disclosed in the '721 patent itself and represents information presented by Schering to the Patent Office during prosecution of the '721 patent.

A patent is shielded under 35 U.S.C. §121 from the use of an earlier issued patent as a reference if the later issued patent was filed as a result of a restriction requirement in the earlier issued patent and is consonant with that restriction requirement. *Bristol-Myers Squibb*, 361 F.3d at 1348. However, the safe harbor of 35 U.S.C. §121 applies only to divisional applications; it does not apply to continuation-in-part applications. *Pfizer*, 518 F.3d at 1362. Because the '721 patent matured from a continuation-in-part application of the '365 patent, the '365 patent is available as a reference against the '721 patent for purposes of double patenting as a matter of law under *Pfizer, Inc. v. Teva Pharms. USA, Inc*., 518 F.3d 1353 (Fed. Cir. 2008).

V. CONCLUSION

For the foregoing reasons, Glenmark respectfully requests that the Court grant summary judgment holding that claims 1-5 and 7-13 are invalid as a matter of law.

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